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Ritchie et al.

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(54) **BIOPSY SYSTEM WITH VACUUM CONTROL MODULE**

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(*) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 988 days.

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(51) **Int. Cl.**
A61B 10/02 (2006.01)

(52) **U.S. Cl.**
CPC ***A61B 10/0275*** (2013.01); ***A61B 10/0283*** (2013.01); *A61B 2010/0225* (2013.01)

(58) **Field of Classification Search**
CPC A61B 10/0233; A61B 10/0266; A61B 10/0275; A61B 10/0283
USPC 600/562, 565, 566; 604/317, 319, 320, 604/321, 322
See application file for complete search history.

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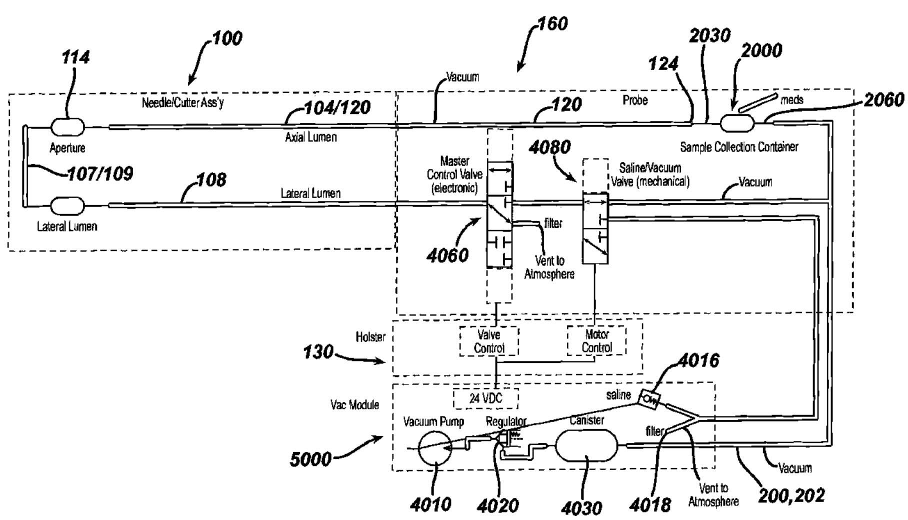
(57) **ABSTRACT**

A biopsy system includes a biopsy device having a translating cutter for severing tissue samples and a vacuum control module. The vacuum control module is separate from the biopsy device. The vacuum control module includes a vacuum pump and vacuum canister, and is portable by a single hand. The vacuum canister and the vacuum control module have complimentary ports that are configured to couple upon insertion of the vacuum canister into the vacuum control module. The complimentary ports provide fluid communication between a vacuum pump in the vacuum control module and a reservoir in the vacuum canister. The biopsy device may be placed in fluid communication with the vacuum pump via the canister without the user having to separately connect any tubes with the canister or pump.

7 Claims, 9 Drawing Sheets



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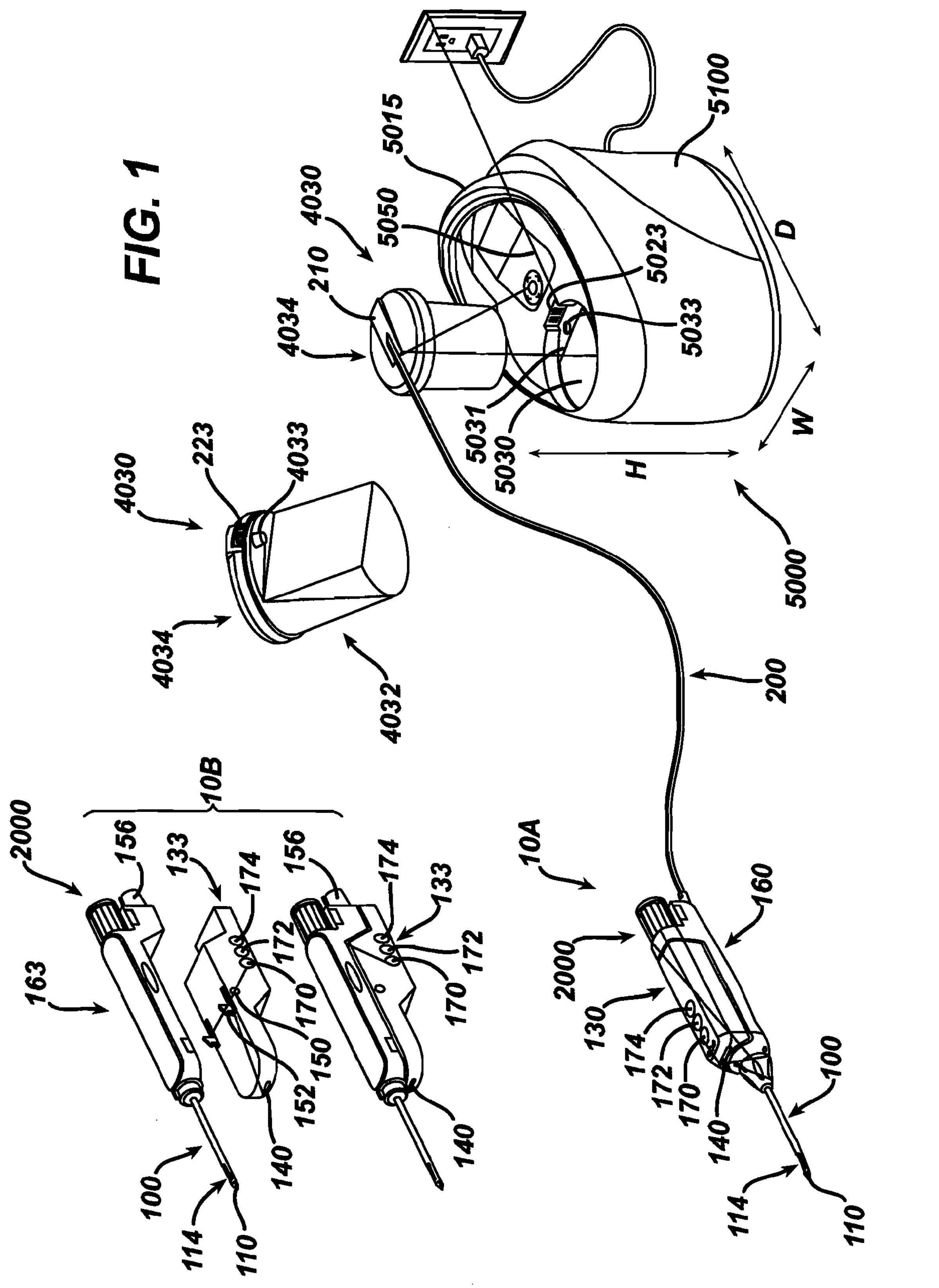
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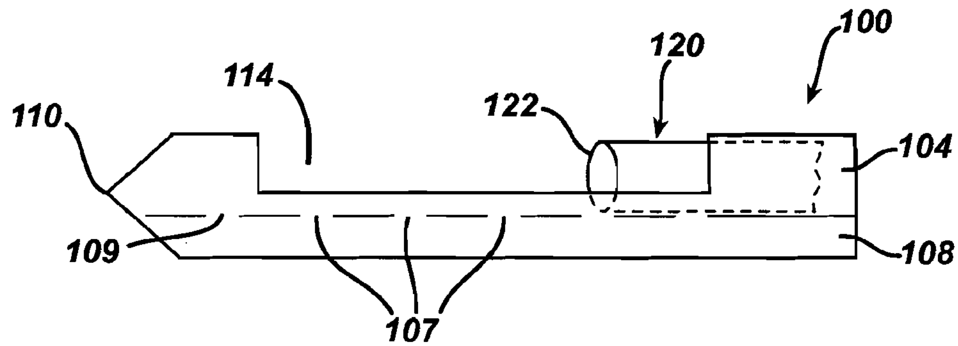
4034
4032
200
10B
2000
156
133
174
163
172
170
150
152
140
100
114
110
10A
160
130

FIG. 1

FIG. 1A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107

FIG. 1B

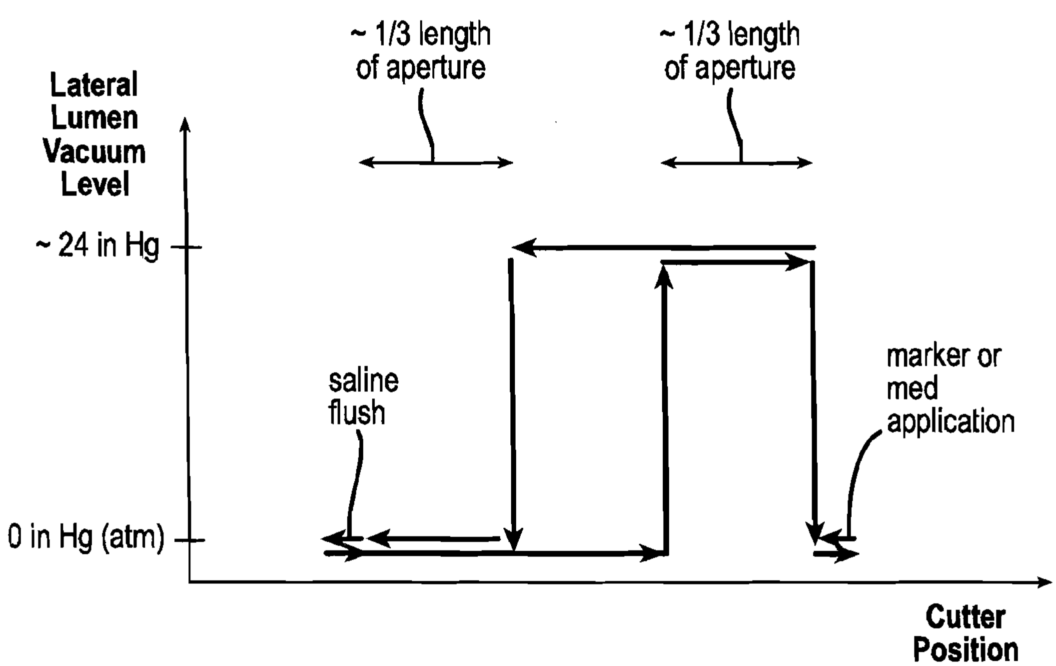
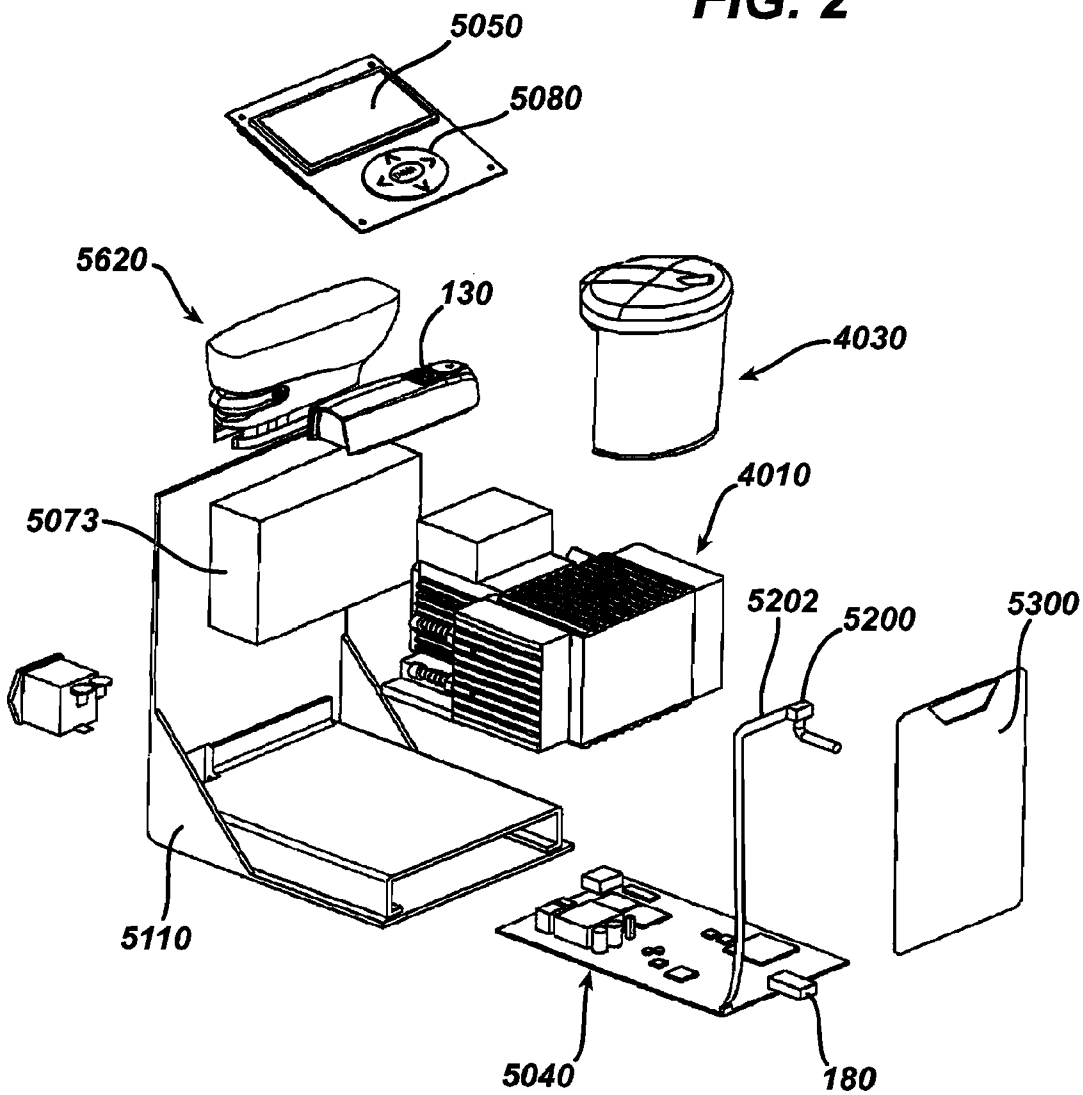

~ 1/3 length of aperture
~ 1/3 length of aperture
Lateral Lumen Vacuum Level
~ 24 in Hg
saline flush
marker or med application
0 in Hg (atm)
Cutter Position

FIG. 2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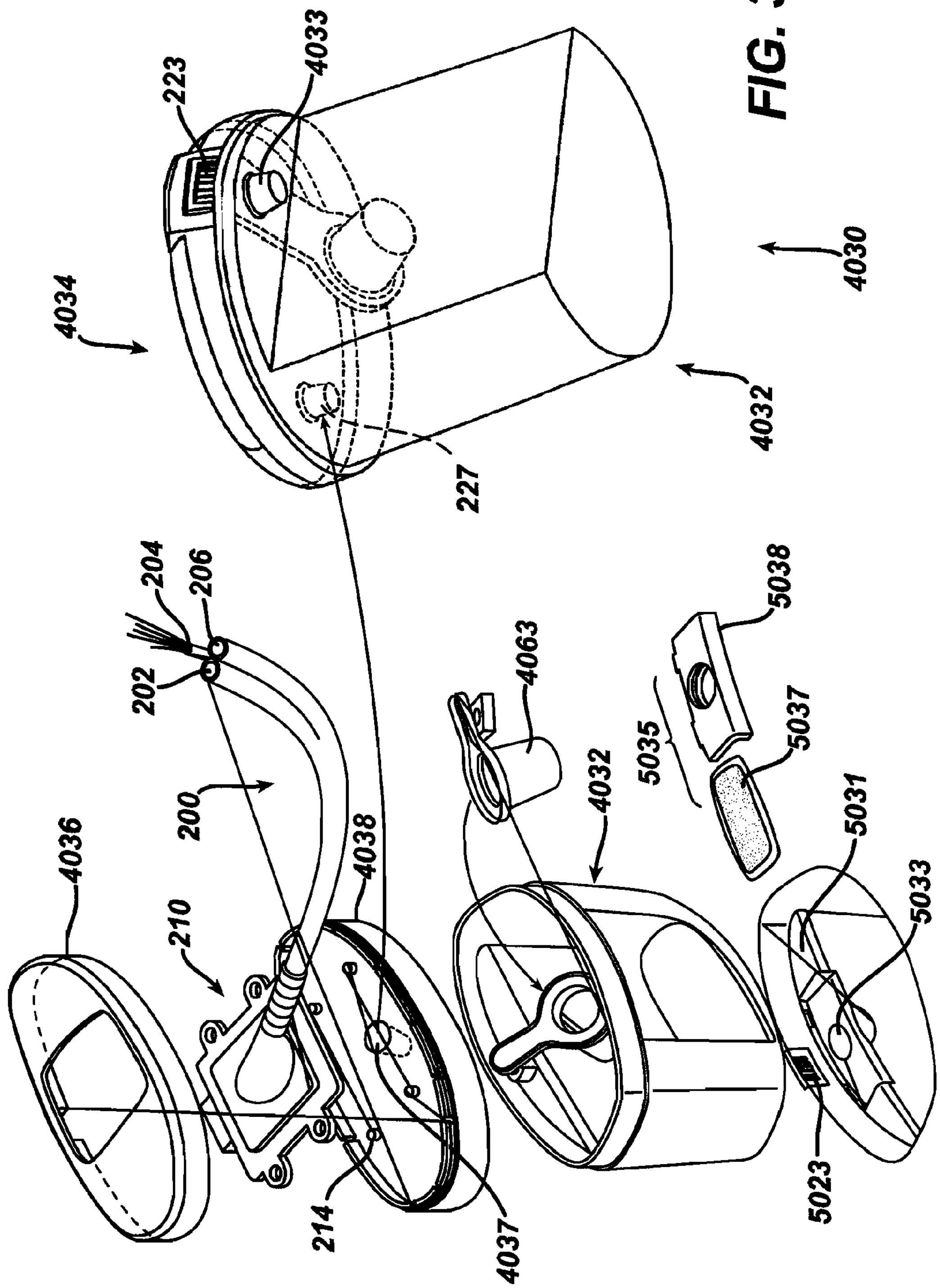
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214
4037

FIG. 3

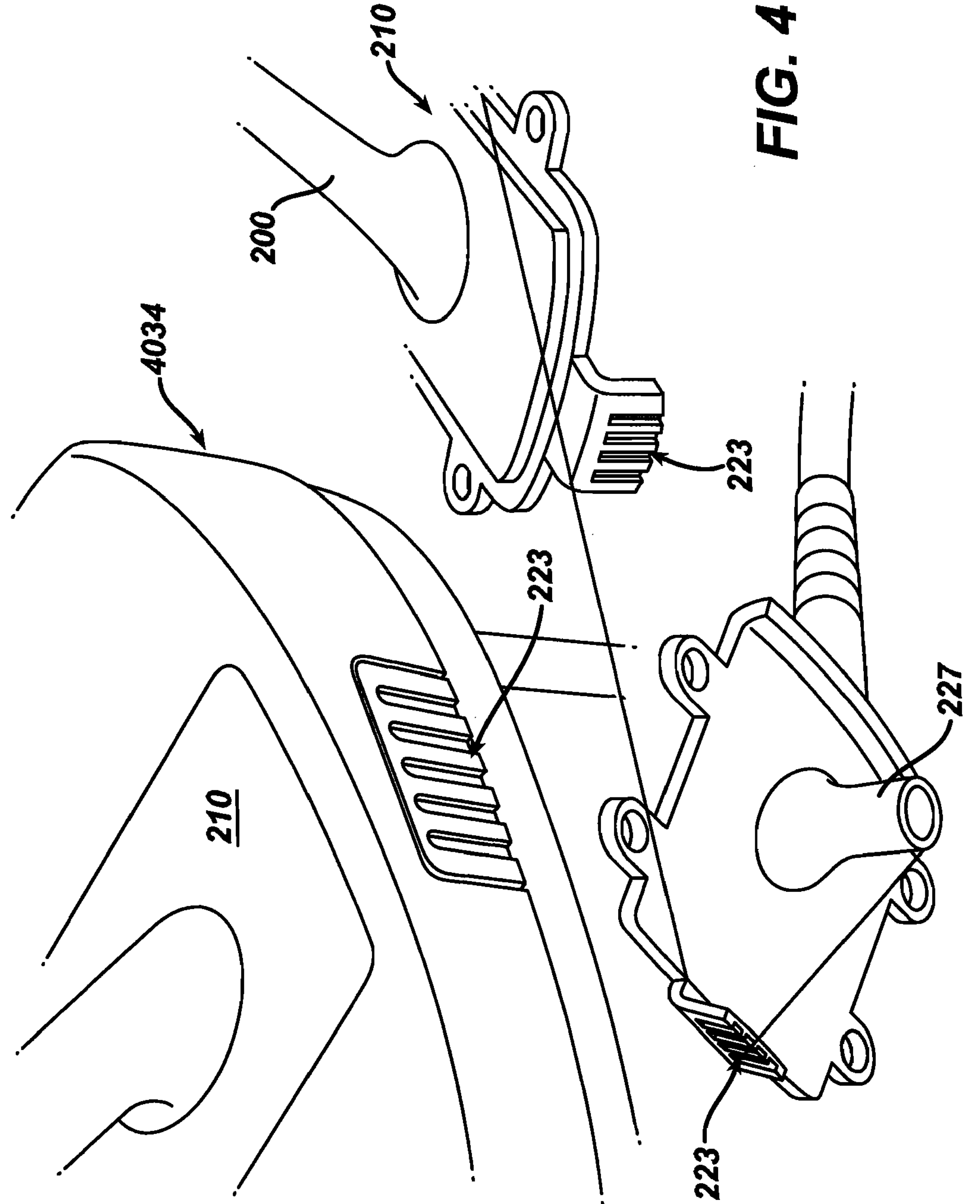


FIG. 4

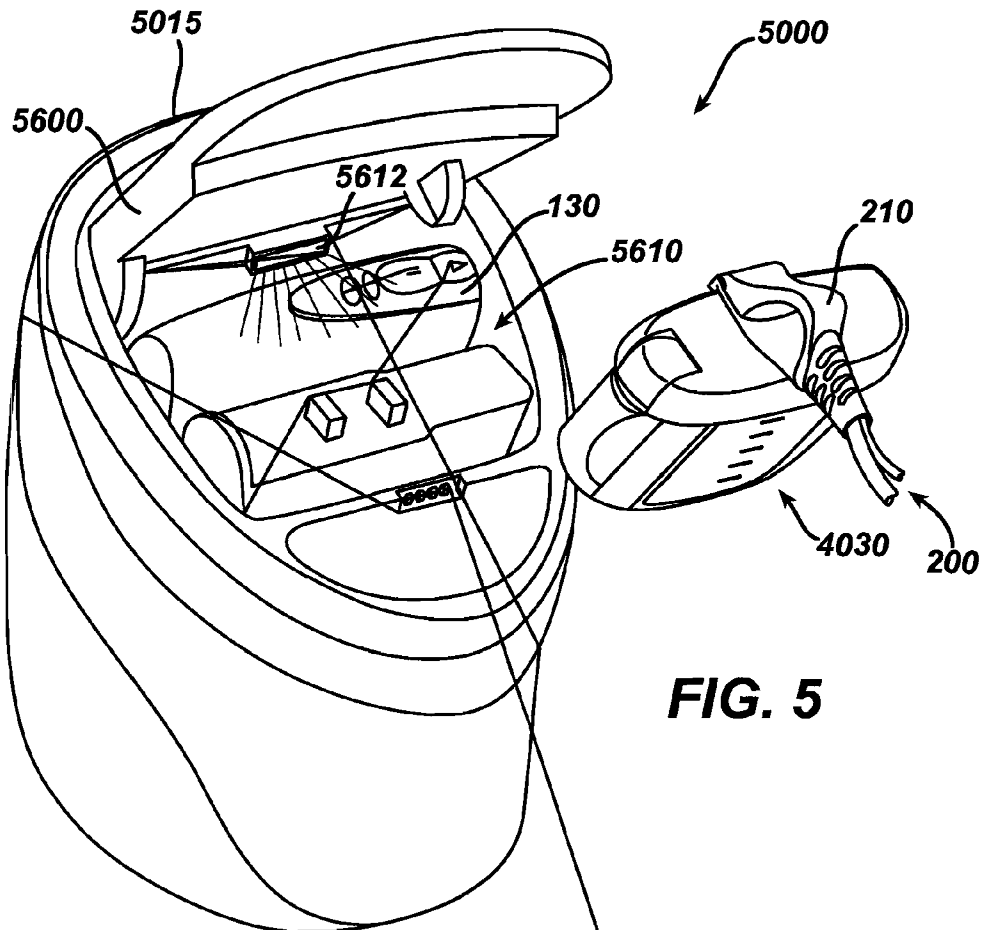


FIG. 5

FIG. 5A

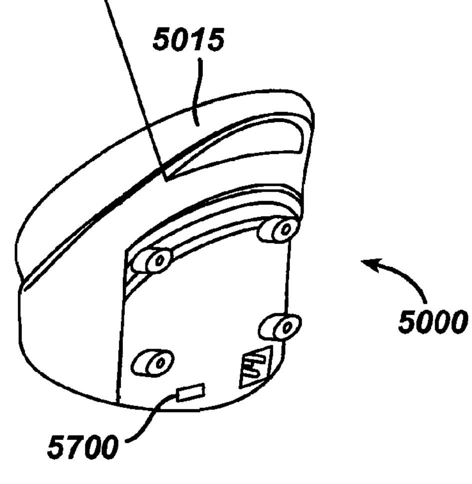
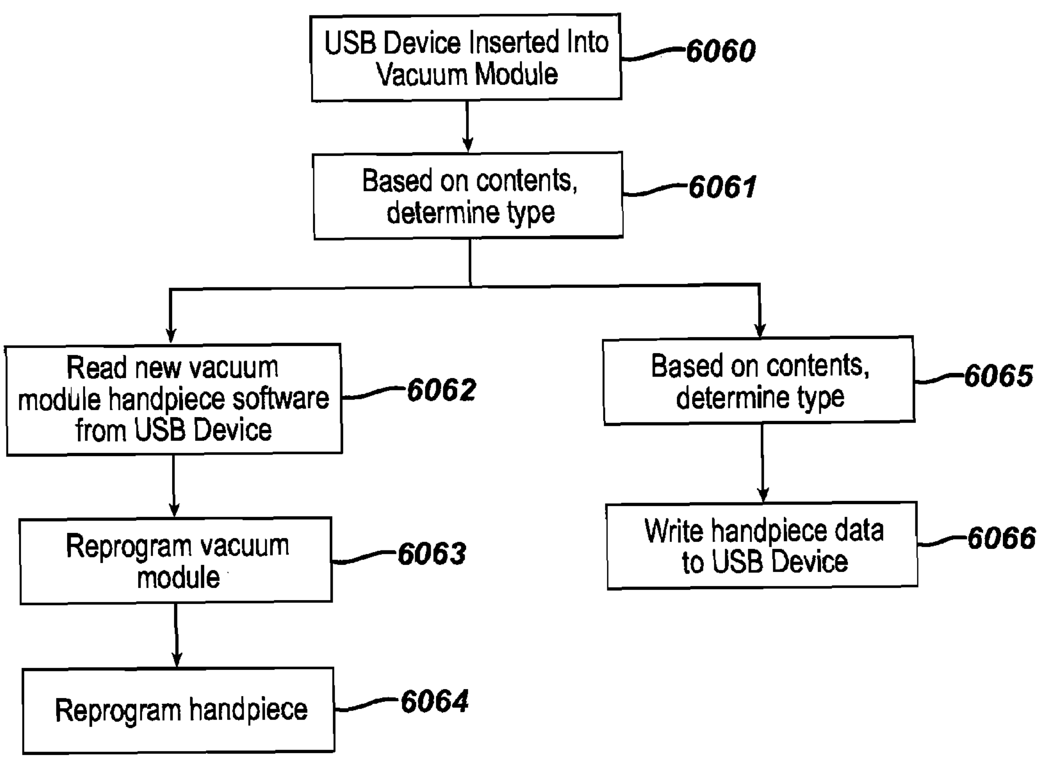


FIG. 6


USB Device Inserted Into Vacuum Module
6060
Based on contents, determine type
6061
Read new vacuum module handpiece software from USB Device
6062
Reprogram vacuum module
6063
Reprogram handpiece
6064
Based on contents, determine type
6065
Write handpiece data to USB Device
6066

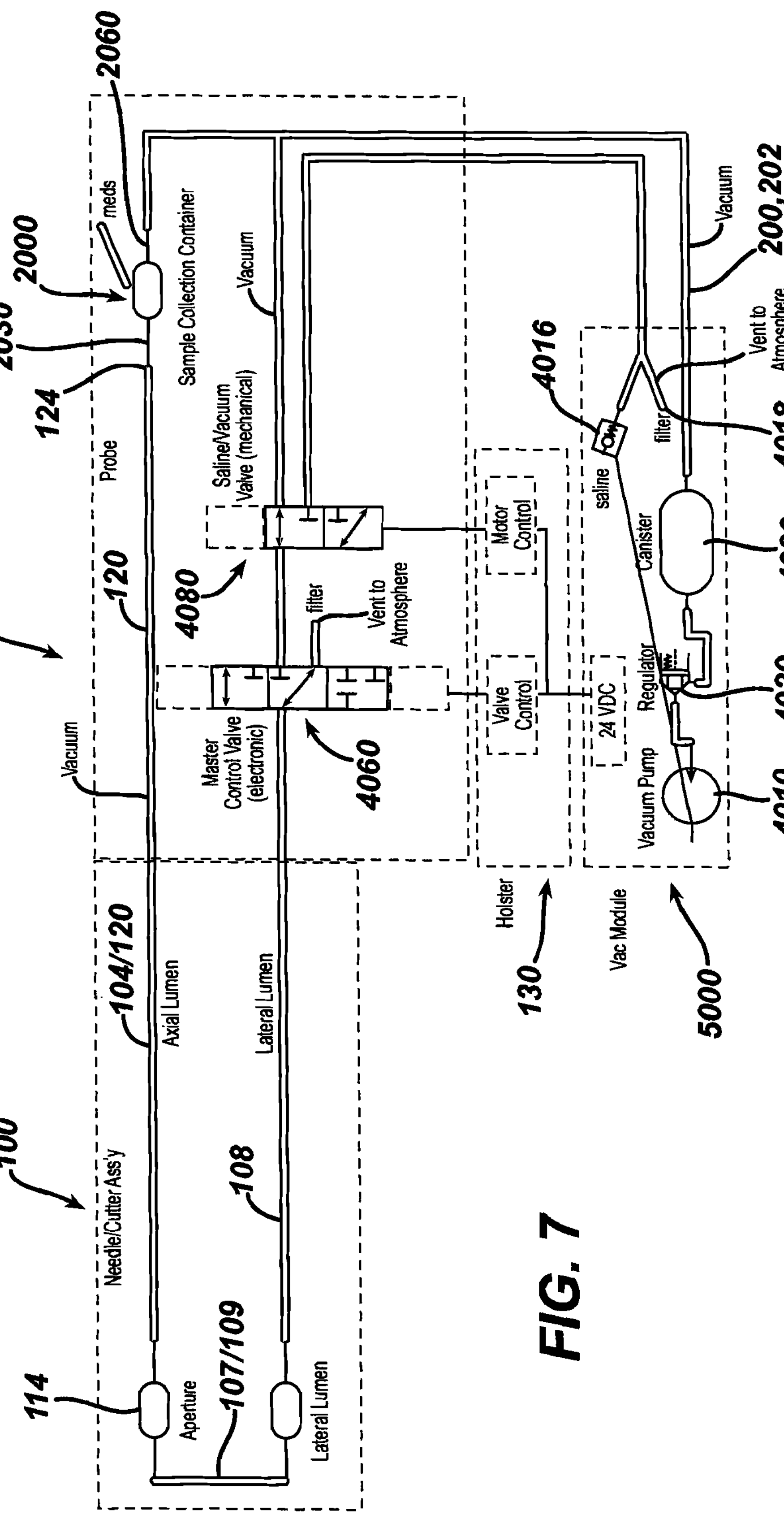

2060
meds
2000
Sample Collection Container
2030
124
Probe
Vacuum
Saline/Vacuum
Valve (mechanical)
4080
160
120
filter
Vent to
Atmosphere
Vacuum
Master
Control Valve
(electronic)
4060
Motor
Control
Valve
Control
Holster
130
24 VDC
Vac Module
5000
4016
saline
Canister
4030
Regulator
4020
Vacuum Pump
4010
filter
4018
Vent to
Atmosphere
Vacuum
200,202
104/120
Axial Lumen
Lateral Lumen
108
100
Needle/Cutter Ass'y
114
Aperture
107/109
Lateral Lumen

FIG. 7

FIG. 8

Action	"Sample" Button (170)	"Clear Probe" Button (172)	"Aspirate/Insert" Button (174)	Aperture (114)	Lateral Lumen (108)	Master Control Valve (4060) Position	Saline/Vacuum Valve (4080) Position
Ready State	---	---	---	closed	sealed/dead-headed	up	up
Sample	press & release or press & hold	---	---	open	vacuum	down	down
				closed	vent	middle	up
Clear Probe	---	press & release or press & hold	---	closed	saline	down	up
Insert Pain or Bleeding Medication or Apply Marker, etc.	---	---	press & release	open	vent	middle	down
Aspirate Cavity	---	---	press & hold	open	vacuum	down	down

BIOPSY SYSTEM WITH VACUUM CONTROL MODULE

PRIORITY

This application claims priority to and incorporates by reference U.S. provisional application Ser. No. 60/869,736, filed Dec. 13, 2006, and U.S. provisional application Ser. No. 60/874,792, filed Dec. 13, 2006.

BACKGROUND

Some embodiments of the present invention relate in general to biopsy devices for obtaining tissue samples from within the body, and more particularly to a biopsy system including a lightweight, portable biopsy control module.

When a suspicious tissue mass is discovered in a patient's breast or another area through examination, ultrasound, MRI, X-ray imaging or the like, it may be necessary to perform a biopsy procedure to remove one or more samples of that tissue in order to determine whether the mass contains cancerous cells. A biopsy may be performed using an open or percutaneous method. Medical devices for obtaining tissue samples for subsequent sampling and/or testing are known in the biopsy art. For instance, a biopsy instrument now marketed under the tradename MAMMOTOME is commercially available from Ethicon Endo-Surgery, Inc. for use in obtaining breast biopsy samples. This device generally retrieves multiple core biopsy samples from one insertion into breast tissue with vacuum assistance.

The following patent documents disclose various biopsy devices and are incorporated herein by reference in their entirety: U.S. Pat. No. 6,273,862 issued Aug. 14, 2001; U.S. Pat. No. 6,231,522 issued May 15, 2001; U.S. Pat. No. 6,228,055 issued May 8, 2001; U.S. Pat. No. 6,120,462 issued Sep. 19, 2000; U.S. Pat. No. 6,086,544 issued Jul. 11, 2000; U.S. Pat. No. 6,077,230 issued Jun. 20, 2000; U.S. Pat. No. 6,017,316 issued Jan. 25, 2000; U.S. Pat. No. 6,007,497 issued Dec. 28, 1999; U.S. Pat. No. 5,980,469 issued Nov. 9, 1999; U.S. Pat. No. 5,964,716 issued Oct. 12, 1999; U.S. Pat. No. 5,928,164 issued Jul. 27, 1999; U.S. Pat. No. 5,775,333 issued Jul. 7, 1998; U.S. Pat. No. 5,769,086 issued Jun. 23, 1998; U.S. Pat. No. 5,649,547 issued Jul. 22, 1997; U.S. Pat. No. 5,526,822 issued Jun. 18, 1996; and US Patent Application 2003/0199753 published Oct. 23, 2003 to Hibner et al.

Some vacuum-assisted biopsy devices may employ a reusable control module that includes a vacuum pump and other control apparatus. Such vacuum control modules may be relatively large and heavy, and may be mounted on wheels or on a wheeled platform so that they can be moved from room to room in a surgical area.

While a variety of biopsy systems have been made and used, it is believed that no one prior to the inventors has made or used a biopsy system as described in the appended claims.

BRIEF DESCRIPTION OF THE DRAWINGS

While the specification concludes with claims particularly pointing out and distinctly claiming the present invention, it is believed the same will be better understood by reference to the following description, taken in conjunction with the accompanying drawings in which:

FIG. **1** is a schematic illustration of a biopsy system according to one embodiment of the present invention;

FIG. **1**A is a schematic illustration of a distal portion of a tissue piercing cannula having a vacuum lumen and a cutter lumen, with the distal portion of the cutter shown in the cutter lumen.

FIG. **1**B is a schematic illustration of the vacuum level provided in a vacuum lumen as a cutter is advanced and retracted in a cutter lumen relative to a tissue receiving aperture.

FIG. **2** is a schematic exploded view illustration of certain components of the vacuum control module depicted in FIG. **1**.

FIG. **3** is a schematic illustration of a vacuum canister that can be used with the biopsy system of FIG. **1**.

FIG. **4** is a schematic illustration of the interface of a multilumen cable and a vacuum canister cover.

FIG. **5** is a schematic illustration of a control module including a handle and a hinged lid.

FIG. **5**A illustrates a USB port positioned on the back surface of the control module of FIG. **5**.

FIG. **6** illustrates various steps that can be performed with respect to a USB device inserted into a USB port on a control module.

FIG. **7** illustrates a pneumatic circuit that may be used with a biopsy system.

FIG. **8** illustrates multiple control states that can be employed in controlling a biopsy device in a biopsy system.

DETAILED DESCRIPTION

FIG. **1** illustrates a biopsy system according to one embodiment of the present invention. The biopsy system of the present example includes a biopsy device **10** having a translating cutter **120** for severing tissue samples, a vacuum control module **5000**, and an umbilicus **200** extending from the biopsy device **10** to the control module **5000**. The umbilicus **200** can be in the form of a cable having multiple lumens for providing one or more of electrical power, vacuum, pneumatics, hydraulics, or saline to the biopsy device **10**. The biopsy device **10** can be a hand held device **10**A such as is suitable for use with ultrasound imaging, or alternatively, a stereotactic device **10**B configured to be mounted on a stereotactic or X-ray table. The vacuum control module **5000** can be a relatively lightweight, portable unit having a smoothly shaped outer cover **5100** and a carrying handle **5015**. The lightweight control module **5000** of this example can be lifted and moved easily by a single person, with one hand. The multilumen umbilicus **200** of this example provides a single connection between the biopsy device **10** and the control module **5000**, eliminating the complexity of having multiple electrical, saline, pneumatic, hydraulic, and/or vacuum lines extending from the biopsy device **10**.

As noted above and as shown in FIG. **1**, biopsy device **10** can be a handheld biopsy device **10**A suitable for use with ultrasound imaging. The biopsy device **10**A can include a reusable holster **130** and a disposable probe unit **160** that is detachable from holster **130**. Together, the holster **130** and the probe **160** form a handpiece that can be comfortably held in and operated with a single hand. Biopsy device **10**B can include a disposable probe unit **163**, and a reusable stereotactic holster **133** having a firing mechanism for firing a tissue piercing portion of the biopsy device into tissue. The firing mechanism may be power driven (e.g., motorized), and may include a button **150** that may be actuated to activate the firing mechanism; as well as firing members **152** that are configured to engage probe **160** to fire at least a portion of probe **160** into tissue. Any suitable configuration for the firing mechanism may be used, to the extent that a firing mechanism is included at all. The stereotactic holster **133** can be configured for operable mounting onto a stereotactic X-ray table. Of course, biopsy device **10**A and biopsy device **10**B may alternatively be used in a variety of other settings or configurations.

The probe units **160** and **163** of the present example include a distally extending tissue piercing portion, such as a cannula **100** extending distally from probe **160**. The cannula **100** can include a distal tissue piercing tip **110** and a tissue receiving aperture **114** spaced proximally of the tip **110**. The cannula **100** can also include a cutter lumen **104** and a vacuum lumen **108**, with passageways **107** and **109** providing flow communication between the lumen **104** and lumen **108** in the distal portion of cannula **100** (FIG. **1**A). The cannula **100** can be inserted into or adjacent to a tissue mass to be sampled, and the biopsy device **10** is operable to obtain a plurality of severed tissue samples with a single insertion of cannula **100** into tissue.

With cannula **100** being inserted into tissue, tissue drawn into the aperture **114** can then be severed by sharpened distal end **122** (FIG. **1**A) of a tubular cutter **120** translating within the cannula **100**. Vacuum can be applied axially through the cutter **120** and also in vacuum lumen **108** to assist in drawing tissue into aperture **114**. FIG. **1**B illustrates graphically a variable vacuum level that can be provided in vacuum lumen **108** as the cutter **120** is translated relative to the aperture **114**. The probe units **160** and **163** can also include a tissue storage assembly **2000**, which can be disposed at a proximal end of the probe unit **160**, **163** or elsewhere. The tissue storage assembly **2000** can be employed to store multiple tissue samples severed by the cutter translating within the cannula **100** and transferred proximally through the hollow cutter **120** to the tissue storage assembly **2000**.

The probe units **160** and **163** of the present example each also include a light **140** positioned near cannula **100**. By way of example only, light **140** may comprise an LED or other source of light, and may be configured to at least partially illuminate a site into which cannula **100** is to be inserted. Probe **163** also has a remote thumbwheel **156**, which may be rotated to rotate the cannula **100** of probe **163** relative to the remainder of probe **163**. Suitable mechanisms for causing such rotation will be apparent to those of ordinary skill in the art in view of the teachings herein. Of course, either probe **160**, **163**, as well as holsters **130**, **133**, may be subject to numerous variations and modifications as desired.

Vacuum control module **5000** of the present example can be portable by a single hand, and may have a weight of no more than about 40 pounds, and in one embodiment a weight of less than about 25 pounds. Alternatively, vacuum control module **5000** may be of any other suitable weight. The control module **5000** handle **5015** is shown extending upward from an upper portion of the unit, with the handle **5015** being the upper most component of the control module **5000**, as shown in FIG. **1**. The vacuum control module **5000** of the present example can have maximum outer dimensions of width W, depth D, and height H, each of which is less than about 1.5 feet. Alternatively, vacuum control module **5000** may have any other suitable dimensions. Vacuum control module **5000** of the present examples further includes a standard power cord for receiving electrical power from a standard electrical outlet.

FIG. **2** illustrates various components of the control module **5000** of the present example. The control module **5000** can include an internal aluminum (or other suitable metal) chassis **5110**, which can directly or indirectly support a vacuum pump **4010**, an AC/DC power supply **5073**, and a microprocessor control board **5040**. A suitable power supply **5073** may include a 250-Watt power supply model GPFC250 Commercial/GPFM250 Medical 250 manufactured by Condor D.C. Power Supplies of Oxnard, Calif. Alternatively, any other suitable power supply **5073** may be used. A suitable vacuum pump **4010** may include a 2-headed diaphragm pump having a maximum flow rate of less than about 18 liters per minute, and providing a maximum vacuum of about 25.1 inches of Mercury (Inch Hg.). Alternatively, vacuum pump **4010** may have any other suitable components and properties. By way of example only, one suitable vacuum pump **4010** may be a model 7006ZVDP-2.3E Diaphragm pump available from Reitschle Thomas, Thomas Products Division of Sheboygan, Wis.

The control module **5000** can also include an LCD display **5050**, or other type of display, supported on an outside surface of the control module **5000**, or elsewhere (e.g., external to control module **5000**, etc.). By way of example only, display **5050** may include a backlit, color LCD display. Alternatively, any other type of display **5050** may be used, or no display **5050** at all. A keypad **5080** may also be provided, near display **5050**, on control module **5000**. Keypad **5080** may comprise capacitive switches or other input devices, and may be used to enter commands to or otherwise interact with control module **5000**. Display **5050** may display operating conditions, menus, or other information, such that display **5050** and keypad **5080** collectively provide a user interface. Of course, a user interface may alternatively be provided using any other suitable components in any other suitable fashion.

In the present example, control module also has an attachment assembly **5200** that is configured to receive an off-the-shelf saline bag **5300**. Attachment assembly **5200** is coupled with a flex circuit **5202**, and is configured to sense the weight of a saline bag **5300**. In particular, control module **5000** may be configured such that it will prevent operation of biopsy device **10** when no weight or insufficient weight is sensed by attachment assembly **5200**, which may indicate that no saline bag **5300** is present or that the saline bag **5300** contains an insufficient amount of saline. In addition or in the alternative, control module **5000** may be configured to inform the user, such as via display **5050**, that the a saline bag **5300** is not coupled with attachment assembly **5200** or that the saline bag **5300** contains an insufficient amount of saline. Alternatively, data from attachment assembly **5200** may be used in any other suitable way, or attachment assembly **5200** may be omitted altogether.

The vacuum control module **5000** of the present example can have a vacuum canister **4030** that is releasably received within an opening **5030** disposed in a generally upward facing outer surface of the control unit **5000**. The vacuum canister **4030** may serve as a vacuum "capacitor" for the biopsy vacuum circuit, and can have a volume of less than about 300 cubic centimeters. More particularly, the vacuum canister **4030** can have a volume of about 200 to about 250 cc. Alternatively, vacuum canister **4030** may have any other suitable capacity or properties.

Referring to FIG. **3**, the umbilicus **200** of the present example can comprise multiple lumens, and can comprise a first lumen **202** for conveying vacuum from the vacuum pump **4010** to the biopsy device **10**, a second lumen **204** for conveying one or more electrical conductors for conveying power and control signals from the control module **5000** to the biopsy device **10**, and a third lumen **206** for conveying saline. Alternatively, umbilicus **200** may have any other suitable number or type of lumens. As yet another variation, one or more lumens **202**, **204**, **206** are provided in separate conduits or cables, instead of being integrated into a single umbilicus **200**. The proximal end of the umbilicus **200** can include a connection terminator **210**. The distal end of the umbilicus **200** can be received in the disposable portion of the biopsy device **10**, such as the probe **160** or the probe **163**, so that electrical power and control signals are directed through the disposable probe **160**, and then to holster **130**. One or more controls (e.g., control buttons **170**, **172**, **174**, etc.) can be located on the reusable holster **130**. Alternatively, the distal end of the umbilicus **200**, or a portion thereof, may be received in holster **130** or elsewhere. Similarly, controls may be located on probe **160**, **163** in addition to or in lieu of controls on holster **130**.

The vacuum canister **4030** of the present example can include a cup or container shaped body portion **4032** and a lid **4034**. The vacuum canister **4030** is configured to be inserted into an opening **5030** in an upwardly facing outer surface of the control module **5000**. The canister **4030** can be supported on a lip **5031** that extends at least partially around the opening **5030**. Of course, there are a variety of alternative ways in which vacuum canister **4030** may be configured; as well as alternative ways in which vacuum canister **4030** may engage with control module **5000**.

In the present example, the body portion **4032** of the canister **4030** includes a male vacuum port **4033** communicating with the interior of the canister **4030**. The port **4033** can sealingly engage a female vacuum port **5033** disposed in an opening in the lip **5031**, when the canister **4030** is inserted into the opening **5030**. In other variations, the lip **5031** or other portion of the control module **5000** may include a male vacuum port **4033**; with the canister **4030** having a complimentary female vacuum port **5033**. In the present example, the vacuum port **5033** can be connected with a flexible hose or tube or other conduit that communicates with the outlet of the vacuum pump **4010** disposed within the control module **5000**. Accordingly, when the canister **4030** is inserted into the opening **5030** in the present example, a vacuum connection is established from the vacuum pump **4010** to the interior of the canister **4030**.

The lid **4034** of the present example is adapted to receive the connection terminator **210** disposed at the proximal end of the umbilicus **200**. The lid **4034** can include a upper, first lid portion **4036** and a lower, second lid portion **4038**. The connection terminator **210** can be captured between the first and second lid portions **4036**, **4038**, and the two lid portions **4036**, **4038** joined together (such as by a snap fit, by adhesive, or by any other suitable means). The position of the terminator **210** between the lid portions **4036**, **4038** can be established by guide pins **212** on the lower lid portion which mate with corresponding guide holes **214** disposed around the perimeter of the terminator **210**. Alternatively, any other suitable structures or features may be used to establish the position of the terminator **210** between the lid portions **4036**, **4038**, if any are used at all. Indeed, lid **4034** may instead be formed of a single piece instead of two lid portions **4036**, **4038**, and umbilicus **200** may be secured relative thereto in any other suitable fashion. The multilumen umbilicus **200** and the vacuum canister **4030** can be provided as separate disposable items or provided together as a unitary disposable item.

As shown in FIGS. **1**, **3**, and **4**, the connection terminator **210** of the present example provides a multi-contact electrical connection **223**, which faces outward from the lid **4034** when the terminator **210** is positioned on the lid **4034**. The control module **5000** includes a mating multi-contact electrical connection **5023**. The multi-contact connection **5023** is disposed adjacent the opening **5030** of the control module **5000**, such that when the vacuum canister **4030** is positioned in the opening **5030**, the electric contact is established between the control module **5000** and the multilumen umbilicus **200** via the contacts **223** and **5023**. It will be appreciated, however, that electrical contact may be provided between control module **5000** and umbilicus **200** using a variety of alternative structures and techniques.

Referring to FIGS. **3** and **4**, the connection terminator **210** can further include a downward facing male vacuum port **227** extending from a bottom surface of the connection terminator **210**. The vacuum port **227** communicates with the vacuum lumen **202** in umbilicus **200**. When terminator **210** is disposed on lid **4034** between lid portions **4036** and **4038**, the vacuum port **227** extends through an opening **4037** in the lower lid portion **4038** to communicate with the interior of the vacuum canister **4030**. Alternatively, vacuum lumen **202** may communicate with the interior of the vacuum canister **4030** using any other suitable structures or techniques.

Accordingly, in the present example, the vacuum canister **4030**, terminator **210**, and control module **5000** are configured such that positioning the canister **4030** in the opening **5030** of the control module **5000** provides an electrical connection and vacuum communication between the biopsy device **10** and the vacuum control module **5000**. In other words, fluid and electrical connections between biopsy device **10** and the vacuum control module **5000** are established merely by inserting the canister **4030** into opening **5030**, such that additional tube connections or cable connections (e.g., connection of a tube with the canister **4030**), etc. need not be established by the user before or after canister **4030** is inserted into opening **5030**. As used herein, the term "fluid" should be read to include a vacuum, pressurized air, atmospheric air, liquids (e.g., saline, blood, etc.), and the like, regardless of whether solid materials (e.g., tissue samples or particles, etc.) are conveyed therewith.

Still referring to FIGS. **3** and **4**, a float **4063** can be positioned in the canister **4030**. The float **4063** is operable to close vacuum port **4033** in the event fluid accumulates in the canister above an acceptable level. A filter assembly **5035** including a filter pad **5037** and filter pad cover **5038** can be provided at the vacuum port **5033** if desired. Of course, like other components described herein, float **4063**, filter assembly **5035**, filter pad **5037**, and filter pad cover **5038** are all merely optional, and may be modified, substituted, supplemented, or omitted as desired.

FIG. **5** provides a schematic illustration of an embodiment of the control module **5000** that includes a hinged cover **5600**. Cover **5600** covers a storage cavity **5610**, similar to tissue storage compartment **5620** of the control module shown in FIG. **2**. The storage cavity **5610** can be sized to store one or more biopsy device holsters **130**. If desired, a plurality of UV light sources **5612** (only one shown) can be positioned near or within cavity **5610**. Light sources **5612** can be configured to be "on" when the cover **5600** is closed (and "off" when the cover **5600** is opened), and can be employed to disinfect or sterilize the item(s) stored in the cavity **5610**. In other embodiments, other components, features, or devices are included to disinfect or sterilize one or more items stored in the cavity **5610**, in addition to or in lieu of having light sources **5612**. In still other embodiments, no features are included for disinfecting or sterilizing items. Similarly, some variations of control module **5000** lack a cavity **5610** altogether.

Referring to FIG. **5**A, one or more Universal Serial Bus (USB) ports **5700** can be provided on an outer surface of the control module **5000**. Alternatively, any other type of port (e.g., an SD card slot, an ethernet port, a serial connection port, a proprietary connection port, etc.) may be provided on control module **5000**. FIG. **6** illustrates a flow chart describing a sequence of operational steps that can be employed when a USB memory device (not shown) is coupled with control module **5000** via port **5700**. Based on the contents of the USB memory device, a course of action can be determined. For instance, based on the contents of the USB memory device, the control module microprocessor control may write vacuum control module data to the USB memory device (e.g., usage time, operational status, first use or first in service date, and the like.) The control microprocessor control may also write biopsy device data to the USB memory device (e.g., usage time, operational status, first use, or first in service date). Alternatively, the vacuum control module **5000** may read new calibration information, software, or software updates, etc., from the USB memory device, reprogram operation of the vacuum module, and/or reprogram operation of the biopsy device **10**. Alternatively, a computer (e.g., desktop or laptop PC), or network (e.g., internet) connection may be made with control module **5000** via port **5700** or in some other fashion.

FIG. **7** is a schematic illustration of a pneumatic configuration that can be used with the biopsy device **10** and vacuum control module **5000** of the present example. FIG. **8** illustrates multiple control states that can be employed in controlling the biopsy device **10**.

As shown in FIG. **7**, the control module **5000** of the present example comprises the vacuum pump **4010**, a regulator **4020**, and a the vacuum canister **4030** disposed in a pneumatic circuit. A master control valve **4060** and a saline/vacuum valve **4080** are shown schematically as being positioned in the disposable probe **160**.

The vacuum provided by vacuum pump **4010** can be directed through the vacuum lumen **202** of umbilicus **200** to the disposable probe **160**, to provide vacuum to the cutter **120** and cutter lumen **104**. This vacuum can be provided without valving, so that the vacuum provided to the interior of cutter **120** and to cutter lumen **104** of cannula **100** is always "on" when vacuum pump **4010** is operating. Alternatively, one or more valves or similar components may be provided in probe **160**, canister **4030**, control module **5000**, and/or elsewhere. The vacuum provided by umbilicus **200** can also provide a vacuum to the vacuum lumen **108** via the two valves **4060** and **4080**. Valve **4080** can be a 3-port/2-position valve, with two input ports. One input port can be connected to the vacuum source and the other input port can be connect to a source of saline **4016** (or alternatively vented to atmospheric pressure through filter **4018**). The output port of valve **4080** communicates with an import port of master valve **4060**. Other suitable configurations and couplings for the ports will be apparent to those of ordinary skill in the art in view of the teachings herein.

The operational position of the valve **4080** can be configured to correspond to the position of the cutter **120**, such as by having cutter **120** extend through the valve **4080** so that the position of the cutter **120** within the valve body determines the operational status (opened or closed) of the valve ports. When the cutter **120** is retracted proximally (e.g., such that tissue aperture **114** is open), the valve **4080** communicates vacuum to the master control valve **4060**. When the cutter **120** is advanced distally (e.g., such that tissue receiving aperture **114** is closed), the valve **4080** communicates saline to the master control valve **4060**. Alternatively, if saline is not available, or not desired, then valve **4080** communicates atmospheric air via filter **4018** to the master control valve **4060**. The valve **4060** can be actuated by a microprocessor controlled motor, by a mechanical link to the cutter **120**, or otherwise. The valve **4080** can be spring loaded in one position, and movement of the cutter **120** (such as movement of the cutter **120** to the distal position) can be employed to change the valve operational position. Alternatively, the operational position of the valve **4080** can be configured to correspond to the position of the cutter **120** in any other suitable way. Furthermore, valve **4080** may be configured such that its operational position does not necessarily correspond with the position of the cutter **120**.

The master control valve **4060** can be a 3-port/3-position valve. One input port can be connected to the output port of the valve **4080**. The second input port can be vented to filtered atmospheric air. The output port of the valve **4060** can be connected to the proximal end of vacuum lumen **108** of cannula **100**. The valve position of valve **4060** can be controlled by the operator of the biopsy device **10** using one or more user control interfaces, such as the control buttons **170**, **172**, **174** listed in FIG. **8** or any other interface. The control buttons **170**, **172**, **174** can be located at any convenient position on the body of the biopsy device **10**, including for instance on handpiece **130**, or elsewhere. The valve **4060** can be actuated by a solenoid, motor, via a link to the cutter **120**, or otherwise.

With reference to FIG. **8**, the "Ready State" of biopsy device **10** corresponds to the cutter **120** being advanced to its distal most position and tissue aperture **114** being closed. In the Ready State, the valve **4080** communicates saline to the master control valve **4060** and the master control valve is positioned to seal off (close) its other ports, including the output port communicating with vacuum lumen **108**. By closing the port to the lateral lumen **108** while in the Ready State, airflow through the device may be minimized, which may allow the pump **4010** to more easily maintain the desired vacuum level at the vacuum canister **4030**.

When the operator depresses the "Sample" button **170** in the present example, the cutter motor is activated to cause the cutter **120** to retract proximally. As the cutter retracts, the valve **4080** changes position to communicate vacuum to the master control valve **4060**. At the same time, the master control valve changes position to communicate a vacuum to the vacuum lumen **108**. With the tissue aperture **114** open, vacuum from vacuum pump **4010** is applied to the cutter **120** (such as via the tissue storage assembly **2000**) and cutter lumen **104** (via the cutter **120**), as well as to the vacuum lumen **108** (via the valves **4080** and **4060**). Vacuum applied to both cutter lumen **104** and vacuum lumen **108** assists in prolapsing tissue into aperture **114** of cannula **100**.

After maintaining this vacuum state for a second or more to ensure tissue has prolapsed into aperture **114**, the cutter **120** is advanced distally (and simultaneously rotated) to close the aperture **114** and severe a tissue sample in the distal portion of the hollow cutter **120**. As the cutter **120** advances distally, the cutter **120** can contact or otherwise actuate the valve **4080** to change the valve position to communicate saline to the master control valve **4060**. Also, as the cutter **120** advances, a microprocessor can be employed to change the master control valve **4060** position to communicate filtered atmospheric air to vacuum lumen **108**, which in turn is communicated via passageways **107**, **109** to the distal face of the severed tissue sample positioned in the distal portion of hollow cutter **120**. The atmospheric air on the distal face of the tissue sample provides a proximal pushing force on the tissue sample, while the vacuum provided in cutter **120** (via the tissue storage assembly **2000**) provides a proximally directed pulling force on the severed tissue sample. The resulting proximally directed force on the tissue sample conveys the tissue sample through the hollow cutter **120** into tissue storage assembly **2000**. Of course, any other suitable structures or techniques may be used to capture a tissue sample and communicate it to a tissue storage assembly **2000**.

In an alternative embodiment, the microprocessor can be employed to change the position of master control valve **4060** to first communicate saline to vacuum lumen **108** for a predetermined period of time, and then change the valve's position to communicate atmospheric air to the lumen **108**.

Accordingly, a fixed volume of saline can be delivered via passageways **107**,**109** to the distal end of hollow cutter **120**, thereby assisting in moving the severed tissue sample proximally through hollow cutter **120** to tissue storage assembly **2000**. The control system can be programmed to return to the Ready State after a predetermined period of time (e.g., one or more seconds).

The biopsy device operator can depress the "Clear Probe" button **172** while in the Ready State (e.g., after having operated the "Sample" button **170** to sever tissue) in order to direct a microprocessor control to cause the cutter **120** to reciprocate slightly to open and close aperture **114** a fraction of an inch (e.g. 0.2 inches), or to any suitable degree. This reciprocation of cutter **120** can be effective to dislodge the tissue sample or otherwise free the sample so that the sample can travel freely through hollow cutter **120**. While the cutter **120** is reciprocating, the vacuum control valve **4060** can be repositioned to communicate saline to the vacuum lumen **108** and through passageways **107**, **109** to provide a pushing force on the distal face of the tissue sample. After a predetermined period of time, the microprocessor can return the pneumatic system to the Ready State.

The operator can depress and release the "Aspirate/Insert" button **174** when the device is in the Ready State to insert medication or a tissue marker into the tissue being sampled or into the site from which a tissue sample has been or will be taken. When the button **174** is depressed in this example, the cutter **120** moves proximally to open aperture **114**. The position of the master control valve **4060** is changed to communicate atmospheric air to the vacuum lumen **108**. Depressing the "Aspirate/Insert" button **174** also turns off the vacuum (such as by either turning off the pump **4010** or opening regulator **4020** to vent pump **4010** outlet to atmosphere, etc.). The tissue marker applier (or medication) can be fed into the proximal end of the cannula **100** through hollow cutter **120**, such as via the tissue storage assembly **2000** or otherwise, with the marker (or medication) being then deployed through the open aperture **114** in cannula **100**. After the marker or medication has been deployed, the user may press any button, which may advance the cutter **120** to return to the Ready State with the master control valve **4060** positioned up.

The operator can depress and hold the "Aspirate/Insert" button **174** to aspirate fluid in the vicinity of aperture **114**. When the operator depresses the button **174** in this example, the cutter **120** moves proximally to open aperture **114**. With the cutter positioned proximally, the valve **4080** communicates vacuum to the master control valve **4060**, and the master control valve **4060** is positioned to communicate vacuum to the vacuum lumen **108**. Accordingly, vacuum is applied to both the lumen **108** and the cutter lumen **104** (because vacuum is provided continuously through cutter **120** to lumen **104** while the pump **4010** operates in this example). The vacuum provided to lumen **104** and lumen **108** aspirates any liquid near the aperture **114**. When the Aspirate/Insert button **174** is released, the pneumatic system is controlled to return the Ready State. The cutter **120** is advanced to close aperture **114**. As the cutter **120** is advanced in this example, the master control valve **4060** is positioned to communicate filtered atmospheric air to the vacuum lumen **108**. Once the aperture **114** is closed, the master control valve **4060** is positioned to close all its ports to attain the Ready State. As with other operational sequences described herein, the foregoing operational sequence is merely illustrative, and any other suitable operational sequences may be used in addition to or in lieu of those explicitly described herein.

The length of the umbilicus **200** from the control module **5000** housing the vacuum pump **4010** to the biopsy device **10** can be relatively long (as much as 20 feet or more in some cases) in order to accommodate movement of the biopsy device **10** in the operating room, or due to limitations of the position of the control module **5000** in magnetic resonance imaging environments. Of course, umbilicus **200** may be of any desired length. In the present example, the vacuum line in the umbilicus **200** can account for a considerable portion of the flow volume that needs to be supplied or maintained by the vacuum pump **4010** and vacuum canister **4030** when the tissue aperture **114** is open. Placing the saline vacuum valve **4080** and the master control valve **4080** at the distal end of the vacuum line (the end associated with the biopsy device **10**) instead of in the biopsy vacuum control unit **5000** may mean that a smaller vacuum pump **4010** and a smaller vacuum canister **4030** can be used. In some conventional biopsy devices, valving may be placed in the control unit that includes the vacuum pump, and the control unit is may be mounted on wheels due to its weight and size. In FIGS. **2-4**, the valves **4060** and **4080** are shown disposed in the biopsy device **10**. The valves can be disposed in a disposable probe portion **160**, **163** that includes the cannula **100** and cutter **120** and/or in a non-disposable (e.g., in the holster **130**) portion of the biopsy device **10**. Such a valve placement may allow a relatively low weight diaphragm vacuum pump **4010** having a flow rate of about 18 liters per minute to be used, as compared to a conventional pump and valve arrangement requiring more than 80 liters per minute. Of course, any desired vacuum pump having any desired properties may be used.

Similarly, the vacuum canister **4030** can be relatively small, with a volume of less than about 300 cubic centimeters, as compared to a conventional vacuum canister having a volume storage capacity of 1200 cc's or more. As a result, a relatively lightweight, hand-portable vacuum control module **5000** can be employed. The vacuum control module **5000** (FIGS. **1**, **2**, and **5**) can weigh less than 25 pounds, can be carried by one hand, and can have height, width, and length dimensions each less than about 1.5 feet. Alternatively, vacuum canister **4030** and control module **5000** may have any other suitable capacity, size, weight, or other properties.

If desired, a foot pedal (not shown) or remote keypad (not shown) can be employed to provide control input or instructions to the biopsy device **10** directly and/or to the vacuum control module **5000**, such as via a connector **180**. The foot pedal and remote keypad can be tethered (e.g., with one or more wires extending from the food pedal/keypad to the vacuum control module **5000**, etc.). Alternatively, "wireless" communication between the foot pedal/keypad and the control module **5000** and/or the biopsy device **10** can be employed. For instance, wireless "Bluetooth" communication and associated hardware and software can be employed to provide wireless control signals to the vacuum control module **5000** and/or the biopsy device **10** without requiring a "line of sight" for signal transmission and reception. Alternatively, an infrared transmitter and receiver can be employed to send and receive control signals. Other ways in which communication may be provided between components of a biopsy system (e.g., between a pedal/keypad and control module **5000**), whether wired, wireless, or otherwise, will be apparent to those of ordinary skill in the art in view of the teachings herein.

While preferred embodiments of the present invention have been shown and described herein, it will be obvious to those skilled in the art that such embodiments are provided by way of example only. Numerous variations, changes, and substitutions will now occur to those skilled in the art without departing from the spirit and scope of the appended claims.

Additionally, each element described in relation to the invention can be alternatively described as a means for performing that element's function.

What is claimed is:

1. A biopsy system comprising:
a biopsy probe comprising:
a cannula having a closed distal end, a tissue receiving port spaced proximally of the closed distal end, a first lumen, and a second lumen in fluid communication with the first lumen through a plurality of passageways, the cannula extending from the probe;
a cutter having a cutter lumen, the cutter configured for translation relative to the tissue receiving port of the cannula for severing tissue;
a tissue storage assembly positioned to receive tissue samples communicated proximally through the cutter lumen, wherein the cutter is configured to transport severed tissue samples proximally through the cutter lumen to reach the tissue storage assembly; and
a first valve disposed on the probe, wherein at least a portion of the cutter extends through the first valve such that the position of the cutter within the valve determines an operational status of at least one port of the first valve, wherein a first operational status of the at least one port of the first valve is operable to vent the second lumen permitting a vacuum applied to the cutter lumen to urge a tissue sample proximally though the cutter lumen, wherein a second operational status of the at least one port of the first valve is operable to provide vacuum to the second lumen permitting prolapse of tissue into the tissue receiving port.

2. The biopsy system of claim 1 wherein the biopsy probe comprises a second valve separate from the first valve.

3. The biopsy system of claim 2 wherein an output port of the first valve communicates with an inlet port of the second valve.

4. The biopsy system of claim 1 wherein the position of the cutter within a valve body is operable to communicate a source of saline with a second valve.

5. The biopsy system of claim 2 wherein proximal retraction of the cutter operates the first valve to communicate vacuum to the second valve.

6. A handheld biopsy device comprising:
a handpiece sized and shaped to be grasped and manipulated by a single hand and without aid of an external support;
a cannula extending from a distal end of the handpiece, the cannula having a closed distal end, a first lumen, a second lumen, and a tissue receiving port spaced proximally of the closed distal end in fluid communication with the first lumen;
a cutter having a cutter lumen, the cutter configured for translation relative to the tissue receiving port of the cannula for severing tissue;
a first valve having a valve housing disposed in the handpiece, wherein the first valve is operable to vent the second lumen to permit the transport of a tissue sample proximally through the cutter lumen by a vacuum applied to the cutter lumen, wherein the first valve is further operable to apply vacuum to the second lumen to prolapse tissue into the tissue receiving port; and
a tissue storage assembly located at the proximal end of the handpiece;
wherein at least a portion of the cutter extends through the first valve housing; and
wherein the cutter is movable within the first valve housing.

7. The device of claim 6 wherein the handpiece is configured to communicate vacuum to the cutter via the tissue storage assembly.

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